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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/657,722 | 09/08/2000 | Pramod K. Srivastava | 8449-115-999 | 8697 |

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER

YAEN, CHRISTOPHER H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1642

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/657,722

Applicant(s)

SRIVASTAVA, PRAMOD K.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,22-31 and 52-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,22-31 and 52-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10&12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. The amendment filed 3/21/2003 (paper no. 12) is acknowledged and entered into the record. Accordingly, claims 20, 21, and 32-51 are canceled without prejudice or disclaimer, and claims 52-55 are newly added.
2. Therefore, claims 19, 22-31, and 52-55 are pending and examined on the record.

Information Disclosure Statement

3. The Information Disclosure Statements filed 12/27/2002 and 3/21/2003 (paper no. 10 and 12) are acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 112, 2nd paragraph

4. The rejection of claim 24 under 35 USC 112, 2nd paragraph for being indefinite in the recitation of the term "low pH" is maintained for the reasons of record. Applicant argues by presenting references that state that low pH is intended to mean acidic conditions, and further argues that one of skill in the art would understand that the said term would emphatically mean acidic conditions. Applicant's arguments have been carefully considered but are not found persuasive. Although scientifically it is understood that a low pH can be an acidic condition, it does not preclude the term from meaning a basic or alkaline pH. The metes and bounds of the term cannot be determined in this case because the term can be interpreted as meaning as stated in the prior office action. For example a "very basic pH" (i.e. pH 14) condition is titrated to a lower pH (i.e. pH 8), of which is a low pH when compared to the initial "very basic pH."

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Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 19, 22-31 and now newly added claims 52-55 under 35 USC 112, 1st paragraph as containing subject matter which was described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor was in possession of the claimed invention at the time of filing is maintained for the reasons of record. Applicant argues that the claims of the instant invention are “product by process claims” and thus are proper because the process by which the product is made further defines the product being claimed. Applicant’s arguments have been carefully considered but are not found persuasive. A careful analysis and review of the revised written description guidelines provided as training materials to the USPTO distinctly describes 6 distinguishing characteristics that must be provide in order to fulfill the written description of a product (see www.uspto.gov/web/offices/pac/writtendesc.pdf). Some of these characteristics include partial structure, physical/chemical properties, functional characteristics, and known or disclosed correlation between structure and function. The specification of the instant invention has only disclosed the general structure of the HSP-peptide complex, but is devoid of disclosing or describing the structure, identity, function, or any characteristics associated with the peptide extracted from the HSP complex. There is a myriad of possible peptides that can be associated with the HSP-complex, of which the instant specification has not described. Absent this information, one of skill in the art cannot readily make a determination of the contents of the claimed peptide composition, the structure of the composition, or any distinguishing

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characteristics associated with the composition, because the peptides isolated from the HSP complex differ and are not necessarily derived from the same protein.

Furthermore, the specification has not taught any common relationship between the different peptides that would allow for the coverage of such a broad genus of structures encompassed in the claimed composition. The specification has not conveyed to one of skill in the art that they were or could be in possession of peptides of which can include virtually any peptide structure or sequence. As such, written description can only be fulfilled provided that the specification discloses a common structure that is representative of the broad class of structures claimed. For these reasons, the rejection is maintained.

NEW ARGUMENTS

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Berliner *et al* (US Patent 5,210,076). The claim is drawn to a composition comprising a recovered peptide admixed with a pharmaceutically acceptable non-toxic carrier. Berliner *et al* disclose a tyrosinase protein wherein the said protein is found in compound comprising a pharmaceutically acceptable carrier. As evidenced by Noessner *et al* (J. Immunology

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2002,169:5424-5432) tyrosinase is a peptide which can be associated with a HSP70 protein thereby forming a complex, and because the claims are drawn to a product by process, and because the product being produced is already known, the process by which the product is made does not carry any patentable weight.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 12.


Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Christopher Yaen
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August 6, 2003